

CLAIMS

1. A method for intraluminal fixation of intravascular devices, substantially grafts or stent-grafts, including the following successive steps:

- a) preparing a special stapler for operation by checking the state of its loading with fastener means and following fitting over the body of this stapler a corresponding intravascular device, substantially graft or stent-graft, with partially reversing, if necessary, one end of this intravascular device, as well as securing the latter on the stapler body via a means for its temporary fixation.
- b) creating by surgical procedure a duct for access to the lumen of an operated blood vessel, substantially the aorta, directly through the wall of this blood vessel;
- c) inserting through said duct into the lumen of an operated blood vessel, substantially the aorta, a special stapler with a corresponding intravascular device, substantially graft or stent, fitted over and secured thereon, and locating this intravascular device in necessary position;

- d) bringing the stapler into operative position for securing the first end of this intravascular device to the wall of the given blood vessel, substantially the aorta;
- e) checking of the matching of mutual location of the first end of this intravascular device, the place of its supposed securing to the blood vessel wall, as well as of the actuator of said stapler with fastener means located near its free end;
- f) generating in said stapler actuator radial forces sufficient for acting on these fastener means, whereby these fastener means, extending from the actuator in radial direction, punch the wall of said intravascular device and surrounding blood vessel wall in such a way, that the distal ends of these fastener means partly extend outside the blood vessel and are bent over on its outer surface to provide a rigid connection of the first end of said intravascular device with the blood vessel wall;
- g) moving said stapler actuator clear of the first end of the wall of said intravascular device, whereby said fastener means remain fixed in the wall of said intravascular device and in the blood vessel wall, securing the first end of intravascular device to a corresponding portion of the blood vessel and preventing thereby any its displacement relative to this blood vessel;

- h) bringing the stapler into inoperative position necessary for its free removal from said intravascular device and from said blood vessel;
- i) removing the stapler from the blood vessel;
- l) making an incision in said intravascular device for access to its lumen;
- m) inserting through said duct and through said incision into the lumen of said intravascular device, substantially graft or stent-graft, another special stapler for securing the second end of this intravascular device to the wall of this blood vessel, substantially the aorta;
- n) bringing the second special stapler into operative position for securing the second end of this intravascular device to the wall of this blood vessel;
- o) bringing to the wall of said intravascular device, at the point of securing its second end to the blood vessel wall, the actuator of said other stapler;
- p) checking the matching of mutual location of the second end of this intravascular device, at the point of its supposed securing with the blood vessel wall, as well as of the actuator of said other stapler with fastener means located near its free end;

- q) generating in said actuator of this stapler radial forces sufficient for acting on said fastener means, whereby these fastener means, extending from the actuator in radial direction, punch the wall of said intravascular device and surrounding blood vessel wall in such a way that distal ends of these fastener means extend in part outside the blood vessel and are bent over on its outer surface to provide a rigid connection of the second end of this intravascular device with the blood vessel wall;
- r) moving said actuator of the other stapler clear of the wall of said intravascular device, whereby said fastener means remain fixed in the wall of said intravascular device and in the blood vessel wall, securing the second end of said intravascular device to a corresponding portion of the blood vessel and preventing thereby any its displacement relative to this blood vessel;
- s) bringing the other stapler in inoperative position necessary for its free removal from said intravascular device and from said blood vessel;
- t) removing the stapler from the blood vessel;
- u) closing by surgical procedure said incision in the intravascular device and said duct for access to the lumen of this intravascular device and to the lumen of the operated blood vessel,

whereby there are provided secure multiple-spot connections of the intravascular device with a blood vessel wall which prevent displacement of this intravascular device from an assigned position due to blood flow and peristaltic oscillations of blood vessel wall.

2. A method according to claim 1, wherein the ends of said intravascular device, substantially graft or stent-graft, are secured to a blood vessel wall via at least one said stapler and using at least two said fastener means, simultaneously more than at two points, substantially near one of the free ends of this intravascular device.

3. A method according to claim 1, wherein the ends of said intravascular device, substantially graft, are secured to a blood vessel wall via a set of at least two said staplers and using in each of these staplers simultaneously at least two said fastener means secured simultaneously more than at two points, substantially near each of free ends of this intravascular device.

4. A method according to claim 1, wherein the ends of said intravascular device, substantially stent-graft, having a broad proximal part and bifurcated distal part are secured to the wall of a blood vessel,

substantially the aorta, via a set of at least two said staplers and using in each of them simultaneously at least two said fastener means.

5. A method according to claim 4, wherein the ends of said intravascular device, substantially stent-graft having a broad proximal part and bifurcated distal part are secured to the wall of a blood vessel, substantially the aorta, via a set of at least two said staplers and using in each of them simultaneously at least two said fastener means, the set containing at least one first stapler for securing the broad proximal part of stent-graft to the aorta wall and at least one second stapler for securing to said aorta wall the bifurcated distal part of the stent-graft.

6. A method according to claim 5, wherein the proximal end of said intravascular device, substantially stent-graft, having a broad proximal part and bifurcated distal part is secured to the wall of a blood vessel, substantially the aorta, in the area of this aorta neck via the first of said staplers comprised in said set and using simultaneously at least two said fastener means.

7. A method according to claim 5, wherein the distal end of said intravascular device, substantially stent-graft, having a broad proximal part and bifurcated distal part is secured to the wall of a blood vessel, substantially aorta, via the second of said staplers and using simultaneously at least two said fastener means, near the free end of one of the branches of the distal part of this stent-graft.

8. A method according to claim 5, wherein the distal end of said intravascular device, substantially stent-graft having a broad proximal part and bifurcated distal part is secured to the wall of a blood vessel, substantially the aorta, via the second of said staplers and using simultaneously at least two said fastener means, near the free end of the other of the branches of bifurcated distal part of this stent-graft.

9. A method according to claim 5, wherein the distal end of said intravascular device, substantially stent-graft, having a broad proximal part and bifurcated distal part is secured to the wall of a blood vessel, substantially the aorta, via the second of said staplers and using simultaneously at least two said fastener means, near the free ends of both branches of the bifurcated distal part of this stent-graft.

10. A stapler for laparoscopic aortic repair by intraluminal fixation of intravascular devices, substantially grafts or stent-grafts, comprising:

- i) a tubular body configured for positioning within a blood vessel, this tubular body being rigid in longitudinal direction and flexible in lateral direction;
- ii) a substantially cylindrical head disposed at the free end of this tubular body and having an inner axial cavity, a proximal end and a distal end, a die and die lid being rigidly mounted at the proximal end of this head, said die and die lid being coaxial with this head and with one another;
- iii) A die for receiving fastener means, substantially U-shaped staples, shaped substantially as a barrel having a proximal end, a distal end, a substantially cylindrical generatrix and an inner axial cavity open on the side of said barrel distal end and terminating in a bottom at said proximal end of the barrel, this bottom having a through axial hole, through, evenly arranged radial slots, and on its end face presented to the die lid – recesses with grooves for receiving fastener means, substantially U-shaped staples, these recesses with grooves being coaxial with said radial slots and provided with means for setting apart the ends of said U-shaped staples, this means are

disposed along the axes of grooves, immediately adjacent to the cylindrical generatrix of said die and are substantially V-shaped;

- iv) a die lid having a through axial hole, a substantially cylindrical generatrix, a proximal and distal end faces, radial slots evenly arranged in the body of the die of said lid near its distal end face and extending onto its cylindrical generatrix, as well as means for retaining the free ends of U-shaped staples and means for separating from the stapler the middles of these U-shaped staples at the end of their working stroke, these means being disposed near the points of intersection of said radial slots with said distal end face and said cylindrical generatrix of said die lid;
- v) a control mechanism disposed at the end of said tubular body opposite to said head and including a substantially cylindrical hollow body with a proximal end and a distal end, with a retaining handle extending from this distal end sidewise at a certain angle, from about 30 degrees to about 90 degrees, and a control lever pivotally mounted on said retaining handle;
- vi) a pressure rod located within said hollow body, having a longitudinal axis, a proximal end and a distal end, this pressure rod being rigid in longitudinal direction and flexible in lateral direction and operatively associated via its distal end with said control lever,

and its proximal end being substantially conical and reciprocally located in the inner axial cavity of said die;

vii) means for transmitting axial force from said pressure rod to said fastener means, substantially U-shaped staples, and for transforming this axial force into radial forces applied to each of these U-shaped staples, located substantially in said inner axial cavity of the die to periodically cooperate with the proximal end of said pressure rod;

viii) a means for temporary fixation on the stapler body of delivered intravascular devices, substantially grafts or stent-grafts, located on this body stapler outside,

whereby said intravascular device is delivered into a required area of the blood vessel and secured on the wall within this blood vessel, the free ends of fastener means, substantially U-shaped staples, punch the wall of said intravascular device and the surrounding blood vessel wall and extend in part outside a corresponding blood vessel to form a rigid connection of said intravascular device with the blood vessel wall.

11. A stapler according to claim 10, wherein said substantially cylindrical hollow body of the control mechanism has a proximal end and a distal end with retaining handle extending from this distal end sideways

at a certain angle, from about 30 degrees to about 90 degrees, this retaining handle being provided with a swing lock and control lever pivotally mounted on said retaining handle, said control lever having a pressure end movably mounted within the hollow body in the clearance between the spring-loaded end of said pressure rod and adjusting screw coaxial with this pressure rod .

12. A stapler according to claim 10, wherein said die for receiving fastener means is shaped as a barrel with a substantially cylindrical generatrix and inner axial cavity open on the side of the distal end of this barrel and terminating in a bottom at the proximal end of said barrel, the die has through, evenly disposed radial slots on its bottom, and on the end face of this bottom presented to said die bottom – recesses with grooves for receiving fastener means, substantially U-shaped staples, and with means for setting apart the ends of the latter, these recesses with grooves have substantially the same depth relative to said end face of the die bottom and are coaxial with the radial slots.

13. A stapler according to claim 10, wherein said die for receiving fastener means, substantially U-shaped staples, is shaped as a barrel with a substantially cylindrical generatrix and inner axial cavity open on the side

of the distal end of this barrel and terminating in a bottom at the proximal end of said barrel, the die has through, evenly disposed radial slots on its bottom, and on the end face of this bottom presented to said die lid—recesses with grooves for receiving fastener means and with means for setting apart the ends of the latter, these recesses with grooves have substantially different depths relative to said end face of said die bottom and are coaxial with the radial slots.

14. A stapler according to claim 13, wherein said recesses with grooves have at least two different depths relative to said end face of the die bottom, recesses with grooves of different depths alternating with one another.

15. A stapler according to claim 10, wherein said fastener means are formed substantially as U-shaped staples and located radially in said grooves of said stapler die to extend radially from these grooves due to radial forces, the free ends of said U-shaped means being disposed on both sides of said means for setting apart the ends of these fastener means located along the axes of said grooves, immediately adjacent to the cylindrical generatrix of said die and being substantially V-shaped;

16. A stapler according to claim 15, wherein said means for setting apart the ends of said fastener means, substantially U-shaped staples, are disposed along the axes of grooves, immediately adjacent to the cylindrical generatrix of said die and are substantially V-shaped, with lateral guiding faces which are substantially curvilinear, concave and diverging from one another in direction from the center of said die towards its cylindrical generatrix, which allows to bend outward the free ends of fastener means during their extension from the die due to said radial forces.

17. A stapler according to claim 15, wherein said means for setting apart the ends of said fastener means, substantially U-shaped staples, are disposed along the axes of grooves, immediately adjacent to the cylindrical generatrix of said die and are substantially V-shaped, with lateral faces, which are substantially radial, concave and diverge from one another in direction from the center of said die towards its cylindrical generatrix, which allows to bend outward the free ends of fastener means during their extension from the die due to said radial forces.

18. A stapler according to claim 10, wherein said die lid is provided with means for retaining the free ends of said fastener means, substantially U-shaped staples, which contain torsion spring elements disposed near the points of intersection of said radial slots with said distal end face and said cylindrical generatrix of this die lid.

19. A stapler according to claim 10, wherein said die lid is provided with means for separating from this stapler the middles of said fastener means, substantially U-shaped staples, at the end of their working stroke, these means containing recesses located near the points of intersection of said radial slots with said distal end face and said cylindrical generatrix of this die lid.

20. A stapler according to claim 10, wherein said die lid is made of a transparent material for checking the state of fastener means, substantially U-shaped staples.

21. A stapler according to claim 10, wherein said pressure rod has a longitudinal axis, substantially conical proximal end, distal end and thrust collar near its distal end, this pressure rod is rigid in longitudinal direction and flexible in lateral direction, the pressure rod being spring-loaded,

operatively associated by its distal end with said control lever and capable of reciprocation by its distal end -within said hollow body of the control mechanism, and by its substantially conical proximal end – within said inner axial cavity of the die.

22. A stapler according to claim 21, wherein said pressure rod has a substantially conical proximal end with a cone vertex angle from about 3 to about 35 degrees.

23. A stapler according to claim 22, wherein said pressure rod has a substantially conical proximal end with a cone vertex angle from about 10 degrees to about 20 degrees.

24. A stapler according to claim 10, wherein said means for transmitting axial force from said pressure rod to said fastener means, substantially U-shaped staples, and for transforming this axial force into radial forces applied to each of these U-shaped staples contain curved L-shaped levers pivotally mounted by the ends of their long arms near the free end of said hollow body and evenly arranged within said inner axial cavity of the die in such a way, that their short arms bent outward relative to the longitudinal axis of the die, are disposed in corresponding through radial

slots on the bottom of this die, said curved L-shaped levers being configured to periodically cooperate by inner faces of their long arms with said substantially conical proximal end of the pressure rod, and by their free ends of short arms bent outward – with the middles of corresponding U-shaped staples.

25. A stapler according to claim 24, wherein said curved L-shaped levers are pivotally mounted by the ends of their long arms on a ring located within said inner axial cavity of the die, in a clearance between the free end of said head and inner ribs of this die extending from the wall of its inner axial cavity in direction to the die longitudinal axis, said ribs having evenly arranged radial slots, and in each of the latter there is movably located a corresponding curved L-shaped lever.

26. A stapler according to claim 10, wherein said die, die lid and fastener means, substantially U-shaped staples located in the die grooves form in combination a single set of the stapler actuator which is configured to be removed from said stapler body and then replaced by other, similar interchangeable sets.

27. A stapler according to claim 10, wherein said means for temporary fixation on the stapler body of delivered intravascular devices, substantially grafts or stent-grafts, located on this stapler body outside contains substantially an adjusting screw with a thrust head located in the distal part of said body of the control mechanism, coaxially with said pressure rod and on the other side of the pressure end of said control lever, as well as fastener means, substantially U-shaped staples, wherewith said adjusting screw is operatively associated via the pressure end of said control lever and said pressure rod.